

UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENT	OR	ATTORNEY DOCKET NO.
08/235.241	04/29/94	FREUDENBERG	W	5552.1164070
			TOUZEAU	EXAMINER
		18M2/0525		
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	DC 20005-3	915	18:11	,
			DATE MAILED:	05/25/95
This is a communication COMMISSIONER OF		n charge of your application. EMARKS		·
This application ha	•	Responsive to communication file		
A shortened statutory period for response to this action is set to expire month(s), days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133				
Part I THE FOLLOW	ING ATTACHMENT(S	6) ARE PART OF THIS ACTION:		
3. Notice of A	eferences Cited by Exa rt Cited by Applicant, P on How to Effect Draw	TO-1449. 4.	Notice of Informal Pate	Patent Drawing Review, PTO-948. ent Application, PTO-152. Sometimes Fort
Dow II CHIMMADY	NE ACTION		PTOL-413	
Part II SUMMARY C	_			•
1. Claims/	<u>'-/4</u>			are pending in the application.
Of the a	bove, claims	,,,,	a	re withdrawn from consideration.
2. Claims	<u></u>			have been cancelled.
3. Claims				are allowed.
4. 🔀 Claims/	1-7 ad	9-14		are rejected.
5. Claims:				are objected to.
6. Claims			are subject to restric	ction or election requirement.
7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.				
8. Formal drawin	gs are required in resp	onse to this Office action.		
9. The corrected or substitute drawings have been received on Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).				
·		e sheet(s) of drawings, filed on aminer (see explanation).	•	n □approved by the
11. The proposed drawing correction, filed, has been approved; disapproved (see explanation).				
12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received been received been filed in parent application, serial no; filed on				
13. Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.				
14. Other				

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

Serial No. 08/235241

Art Unit 1811

- 15. Applicant's arguments have been fully considered, but have not been found to be convincing.
- 16. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 17. Claims 1-7 and 9-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 never recites that factor VIII:C is part of the solution. Factor VIII:C should be recited after "containing" in order to claim it properly as part of the solution.
- as being unpatentable over Meyers et al. (Meyers). Meyers discloses a large scale adaptation of a recently reported glycine precipitation method for the production of Factor VIII:C concentrate. This method includes adding aluminum hydroxide to a glycine buffer to reduce the level of protein contamination in the final preparation. Furthermore, the resultant product was virus-inactivated by the incorporation of the organic solvent and detergent (TNBP and T80) (abstract). At the industrial level, this method gave 185 IU of FVIII:C activity per liter of starting

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plasma, which the Examiner deems to be at least equivalent to Applicants' yield. Although he does not teach a pharmaceutical containing a solution, he does teach that his concentrate is considered to be suitable for clinical use (page 146, column 1, last 3 lines). Thus, the preparation of a solution with Factor VIII:C activity containing a basic amino acid such as glycine and a nonionic detergent containing a high activity for clinical use would have been obvious to one of ordinary skill in the art in the light of Meyer's disclosure.

19. Claim 13 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. § 112, second paragraph.

Any inquiry concerning this communication should be directed to P. Lynn Touzeau, Ph.D at telephone number (703) 308-0196.

PLT 16 1995

SUPERVISORY PATENT EXAMINER GROUP 1800